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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/924,320	08/07/2001	Mark Huang	P893 US	3586

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MEDTRONIC VASCULAR, INC.
IP LEGAL DEPARTMENT
3576 UNOCAL PLACE
SANTA ROSA, CA 95403

EXAMINER

BAXTER, JESSICA R

ART UNIT	PAPER NUMBER
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3733

DATE MAILED: 11/15/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/924,320

Applicant(s)

HUANG, MARK

Examiner

Jessica R. Baxter

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 August 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4-26 and 28-33 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,4-26 and 28-33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1, 4, 6-10, 12, 14, 17, 19-22, 24, 25 and 28-32 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,913,871 to Werneth et al.

Werneth discloses a balloon stent assembly comprising a balloon including an outer non-tacky first layer and an inner second layer (Column 5 lines 21-23), the outer first layer covering only a limited portion of the inner second layer; and a stent disposed on the balloon (stent 20); wherein the first layer flows into gaps formed in the stent when the balloon stent assembly is heated to a predetermined temperature (Column 5 lines 56-67), and retains the stent on the balloon during intravascular movement and the inner second layer does not flow into the gaps; wherein the outer and inner layers comprise a co-extruded laminate (Column 6 lines 64-67); wherein the outer layer comprises a functionalized material (Column 7 lines 6-67); wherein the outer layer comprises a first material of polyethylene and the inner layer comprises a second material different from the first material (Column 7 lines 6-67).

Werneth discloses a method comprising mounting the stent onto the balloon, the balloon including an inner layer and an outer layer, the stent including gaps, the stent covering at least 55 percent of the balloon; sheathing the mounted stent and balloon with a sheath; heating the mounted stent and balloon; and flowing an outer layer of the balloon into

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the gaps formed in the stent while an inner layer of the balloon does not flow, and while the balloon is heated (Column 5 line 56-Column 6 line 67).

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 2, 16 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Werneth et al. '871 in view of WO 95/33422 to Stoltze et al.

Werneth discloses the claimed invention except for the claimed temperature range.

Werneth discloses that the device is heated to about 190°F (87.8°C) but that the temperature that it is heated to could be lower depending on the outer layer material (Column 6 lines 33-54 and Column 7 52-67). Stoltze teaches that the balloon may be heated to a temperature between 50 and 70°C for a certain period of time in order to soften the outside of the balloon (Page 14 lines 19-23). It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the device of Werneth with the temperature range of Stoltze in order to soften the outside of the balloon to embed the stent in the balloon.

5. Claims 26 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Werneth et al. '871 in view of WO 95/33422 to Stoltze et al.

Werneth discloses the claimed invention except for the step of pressurizing the balloon. Stoltze teaches that the balloon is pressurized to urge it towards the inner wall of the sheath and thus depress the stent into the balloon surface (Page 14 lines 23-28). It would have been obvious to one having ordinary skill in the art at the time the invention was made to pressurize the balloon of Werneth in order to help depress the stent into the surface of the balloon.

6. Claims 5 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Werneth et al. '871 in view of U.S. Patent No. 5,797,877 to Hamilton et al.

Werneth discloses the claimed invention except for the outer layer comprising a tie layer. Hamilton teaches including a tie layer in order to improve softness and foldability of the balloon (Column 4 lines 60-65). It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the device of Werneth with a tie layer in order improve the softness and foldability of the balloon.

7. Claims 11, 13 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Werneth et al. '871 in view of U.S. Patent No. 5,807,327 to Green et al.

Werneth discloses the claimed invention except for the stent retention force. Green teaches that the use of the material urethane will create a suitable retention force (Column 8 lines 55-60). It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the device of Werneth with the stent retention force of Green in order to prevent slippage of the stent from the balloon prematurely.

Response to Arguments

8. Applicant's arguments filed 23 August 2005 have been fully considered but they are not persuasive.

9. Applicant has amended the claims to include the limitation “ the outer first layer covering only a limited portion of the inner second layer.” The applicant points out that support for this amendment is present in paragraph 0021 and in the figures. Paragraph 0021 points to Figures 1 and 2 to show the limited portion that the outer first layer covers. In Figure 2, the outer first layer covers the entire inner second layer. It is not clear how Werneth et al. '871 does not meet the claimed limitation, since applicant has clearly shown an embodiment where the outer first layer is limited to the entire inner layer. Therefore, the rejection over Werneth et al. '871 is proper.

Conclusion

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jessica R. Baxter whose telephone number is 571-272-4691. The examiner can normally be reached on M-F 8:30AM - 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jessica R Baxter
Examiner
Art Unit 3733


jrb


EDUARDO C ROBERT
PRIMARY EXAMINER